

## 1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Kam Leung, Ph.D., RAC  
Senior Regulatory Affairs Specialist

Address: Nobel Biocare USA LLC  
22715 Savi Ranch Parkway  
Yorba Linda, CA 92887

Telephone: (714) 282-4800, ext. 7842

Facsimile: (714) 282-9023

Date of Submission: August 1, 2007

Classification Name: Endosseous dental implant abutment (21 CFR 872.3630)

Trade or Proprietary  
or Model Name: NobelActive Zirconia Abutment

Legally Marketed Device(s): SFB & CFB Angled Abutments (K062749)  
Esthetic Zirconia Abutment (K031719)

Device Description:

NobelActive Zirconia Abutments are artificial tooth abutments designed to fit and function on the NobelActive Implants. It is an internal hexagonal design similar to the previous SFB (renamed NobelActive) Abutments. The material of construction is the same as the previous Esthetic Zirconia Abutments. The NobelActive Zirconia Abutments differ from the predicate device in trade name and material of construction.

Indications for Use:

NobelActive Zirconia Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation in the anterior region.



FEB 22 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Nobel Biocare AB  
C/O Mr. Herbert Crane  
Director, Global Regulatory Affairs  
Nobel Biocare USA, LLC  
22715 Savi Ranch Parkway  
Yorba Linda, California 92887

Re: K072129  
Trade/Device Name: NobelActive Zirconia Abutment  
Regulation Number: 21 CFR 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: NHA  
Dated: February 8, 2008  
Received: February 11, 2008

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

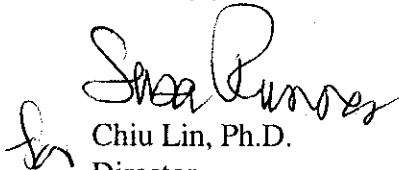
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", is written over the typed name. To the left of the signature is a small, stylized handwritten mark.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known):

Device Name: NobelActive Zirconia Abutment

Indication For Use:

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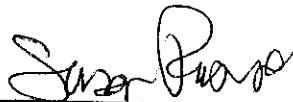
Prescription Use ☒ \_\_\_\_\_  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_\_.  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices